REMARKS OF

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BEFORE THE FDA AND

PROPRIETARY ASSOCIATION SYMPOSIUM

ON SELF CARE

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AS CHAIRMAN OF THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT, I RECEIVE MANY INVITATIONS TO SPEAK. AFTER 9 YEARS ON THE JOB, I STILL MARVEL AT THE ENORMITY OF THE ISSUES WHICH THE SUBCOMMITTEE IS RESPONSIBLE FOR, AND THE DIVERSITY OF ORGANIZATIONS INTERESTED IN THEM. WE HAVE AUTHORITY OVER MEDICARE AND MEDICAID; PUBLIC HEALTH PROGRAMS; BIOMEDICAL RESEARCH; FOOD, DRUG AND MEDICAL DEVICE REGULATION; AND ENVIRONMENTAL PROTECTION THROUGH THE CLEAN AIR AND SAFE DRINKING WATER ACTS. WHAT UNITES THIS ARRAY OF DIVERGENT ISSUES IS OUR RESPONSIBILITY FOR PROMOTING AND MAINTAINING THE PUBLIC HEALTH.

AS YOU CAN IMAGINE, WITH JURISDICTION SO BROAD IT IS REWARDING TO FIND CONSENSUS AMONG EXPERTS AND MEMBERS OF CONGRESS ON AN ISSUE. WE ALL AGREE THAT WHETHER FACED WITH FEDERAL BUDGET DEFICITS OR SURPLUSES, WE CAN NOT AFFORD TO TREAT DISEASES WE CAN PREVENT.

SELF CARE

IN THE FACE OF THE DOUBLE CURSE OF PERSISTENT FEDERAL DEFICITS AND THE RISING COST OF HEALTH CARE, OUR ABILITY TO ADDRESS SERIOUS HEALTH CARE PROBLEMS IS SEVERELY CURTAILED. IN THIS CLIMATE, IT IS CLEAR THAT WE MUST FIND NEW WAYS TO PREVENT DISEASE AND LESS EXPENSIVE WAYS TO TREAT ILLNESS.

YEARS AGO OUR MOTHERS TOLD US THAT AN OUNCE OF PREVENTION IS WORTH A POUND OF CURE. GOOD ADVICE. THERE IS WISDOM TO BE FOUND IN OLD ADAGES. UPDATED TO 1988, AND PARTICULARLY GIVEN THE INTERESTS OF THOSE OF YOU HERE TODAY, IT COULD BE SAID THAT PENNIES SPENT ON SELF CARE ARE WORTH DOLLARS SPENT ON HEALTH CARE.

THERE IS A NEW GENERATION OF AMERICANS TODAY WHO ARE FOLLOWING THIS ADVICE. FOR THEM, GOOD HEALTH IS A DRIVING, MOTIVATIONAL FORCE. THEY HAVE MADE HEALTH CLUBS PROFITABLE BUSINESSES. THEY HAVE PUT SALAD BARS IN FAST FOOD RESTAURANTS. THEY HAVE ELEVATED JOGGING TO THE LEVEL OF A NATIONAL PASSION. THERE IS ENORMOUS PUBLIC INTEREST IN PERSONAL FITNESS AND DIET. THIS TREND IS ENCOURAGING. IT IS NOT A FAD. IT IS A PERMANENT CHANGE IN AMERICAN LIFESTYLE.

THESE AMERICANS SEEK A LIFE WITH MINIMAL RELIANCE UPON EXPENSIVE AND SOPHISTICATED MEDICAL CARE SERVICES.

AS A MEMBER OF CONGRESS CONCERNED WITH PUBLIC HEALTH, I SEE SELF CARE IN THIS BROADER CONTEXT. CERTAINLY IT INCLUDES SELF MEDICATION. BUT THE ESSENCE OF SELF CARE -- FROM A PUBLIC HEALTH PERSPECTIVE -- IS INDIVIDUALS TAKING A WIDE VARIETY OF PERSONAL ACTIONS THAT PROMOTE AND

MAINTAIN THEIR HEALTH.

PRACTICING SELF CARE MEANS GOING FOR NECESSARY PREVENTIVE HEALTH SERVICES SUCH AS PRENATAL CARE, PERIODIC PHYSICALS, AND REGULAR DENTAL CHECK-UPS. IT MEANS HEALTHY LIFESTYLES SUCH AS ADEQUATE EXERCISE, NOT SMOKING, NOT DRINKING EXCESSIVELY, EATING A HEALTHY DIET AND WEARING A SEAT BELT.

WE KNOW THESE SELF CARE ACTIVITIES PAY OFF. OBESITY CAN BE PREVENTED OR CONTROLLED. CARDIOVASCULAR DISEASE CAN BE REDUCED THROUGH DIET AND EXERCISE. QUITTING OR NEVER SMOKING WILL DRAMATICALLY REDUCE PERSONAL HEALTH RISKS. DIETS RICH IN FIBER AND LOW IN FAT MAY REDUCE AN INDIVIDUAL'S RISK OF CANCER.

GOOD ADVICE. IF FOLLOWED, WE CAN HAVE A STRONGER, HEALTHIER POPULATION. IT IS CERTAINLY GOOD NEWS TO A FEDERAL BUDGET BESET BY RISING HEALTH CARE COSTS.

INFORMATION IS KEY

CALL IT SELF CARE, OR CALL IT HEALTHY LIFE STYLES. IT IS AN IMPORTANT NATIONAL OBJECTIVE. BUT -- AND THIS IS AN IMPORTANT BUT -- MANY OF THE ACTIVITIES WE DESCRIBE AS SELF CARE ARE HEAVILY DEPENDENT ON SUCCESSFULLY COMMUNICATING TO THE PUBLIC THE LATEST THINKING OF PUBLIC HEALTH AND MEDICAL EXPERTS.

THE LABELING, THE ADVERTISEMENTS, THE PUBLIC HEALTH MESSAGES ARE ESPECIALLY IMPORTANT IN THE AREAS OF DIET AND SELF MEDIATION. SCIENCE BASED INFORMATION IS THE FOUNDATION UPON WHICH DECISIONS ABOUT DIET AND

OVER-THE-COUNTER DRUGS ARE MADE. THE PUBLIC MUST BE ADVISED AS TO THE FOODS THAT COMPRISE A NUTRITIOUS DIET AND HOW TO EFFECTIVELY USE OVER-THE-COUNTER MEDICATIONS. INFORMATION MUST BE ACCURATE AND TRUTHFUL. AS IMPORTANT, IT MUST BE PRESENTED IN A CLEAR AND CONCISE FASHION.

INCREASINGLY THIS HEALTH CONSCIOUS GENERATION IS DEMANDING INFORMATION THAT IN AN EARLIER TIME WAS THE DOMAIN OF SCIENTISTS, DOCTORS AND NUTRITIONISTS.

IN CLASSIC ECONOMIC THEORY, INFORMATION IS THE SELF-CORRECTING FEATURE OF THE MARKETPLACE. INFORMATION ENCOURAGES EVERYONE TO USE RESOURCES EFFICIENTLY.

THE REGULATION OF THE FAIR USE OF INFORMATION -- DESCRIPTIONS, CLAIMS, WARNINGS OR ADVERTISING -- IS ROUTINELY ACCEPTED AS PART OF THE STOCK MARKETS AND BOND SALES. IT IS ADVOCATED BY THE MOST RESPECTABLE OF CONSERVATIVES. IT IS THE FOUNDATION OF FINANCIAL MARKETS.

BUT NUTRITION AND OVER-THE-COUNTER DRUGS ARE DIFFERENT MARKETS AND ARE EVEN MORE DEPENDENT ON INFORMATION.

NUTRITION PRODUCTS AND OVER-THE-COUNTER DRUGS ARE NOT LIKE OTHER PRODUCTS. IF CARS OR TELEPHONES OR EVEN BONDS DON'T LIVE UP TO MANUFACTURERS' CLAIMS, SUCH FAILINGS ARE EASY TO DISCOVER AND ACT ON. IF THESE GOODS HAVE PARTICULAR DISADVANTAGES, THEY CAN BE SEEN OR FOUND.

BUT WITH FOODS OR DRUGS, THIS INFORMATION MARKET IS MORE DIFFICULT. SUCCESS IS NOT OBVIOUS IMMEDIATELY, NOR IS FAILURE. AND THE WRONG GUESS CAN HAVE SEVERE CONSEQUENCES.

CONSUMERS CANNOT SEPARATE FOODS THAT PREVENT CANCER FROM FOODS THAT DO NOTHING. CONSUMERS HAVE NO INDEPENDENT WAY TO DETERMINE THE BEST MEDICINES FOR THEIR ILLNESS.

IT IS CLEAR TO ME THAT THE QUESTION IS NOT WHETHER TO INFORM AND REGULATE, BUT HOW IT CAN BEST BE DONE. IN A SOCIETY THAT IS SOMETIMES OVERWHELMED BY INFORMATION AND TECHNOLOGY, WE MUST ALL DECIDE HOW MUCH GOVERNMENT INTERVENTION IS HELPFUL:

- GOVERNMENT CAN MAKE THE ENTIRE DECISION FOR THE PUBLIC, AS ALL FIFTY STATES DO WHEN THEY REQUIRE THAT CHILDREN BE IMMUNIZED AGAINST POLIO.

- GOVERNMENT CAN REGULATE THE PUBLIC'S DECISION, AS IT DOES BY MAKING SOME DRUGS AVAILABLE ONLY BY PRESCRIPTION.

- GOVERNMENT CAN REQUIRE DISCLOSURE OF DANGER, AS IT DOES WITH CIGARETTES.

- GOVERNMENT CAN REQUIRE PROOF OF BENEFITS, AS IT IS SUPPOSED TO UNDER BOTH THE FDA LAW FOR DRUGS AND THE FTC LAW FOR ADVERTISING.

- OR GOVERNMENT CAN HOPE THAT PRIVATE ENTERPRISE WILL SOMEHOW INFORM THE PUBLIC AND THAT THE PUBLIC WILL RECOGNIZE FALSE CLAIMS.

I AM SURE THAT NONE OF YOU WILL BE SURPRISED TO KNOW THAT I BELIEVE THAT THE FEDERAL GOVERNMENT HAS GREATER RESPONSIBILITY THAN MERELY TO HOPE FOR THE BEST.

I KNOW THAT THIS GROUP IS CONCERNED WITH DISTINGUISHING TRUE BENEFITS FROM GOOD GUESSES. NO ONE BENEFITS FROM MISINFORMATION.

SELF MEDICATION

NOWHERE IS THE NEED FOR INFORMATION GREATER THAN WHEN CONSUMERS ACT AS THEIR OWN DOCTORS AND NURSES.

CONSUMERS LIKE THE OPPORTUNITY TO DECIDE ON THE MEDICATIONS THEY TAKE FOR MINOR AILMENTS. THEY LIKE BEING IN CONTROL OF MINOR HEALTH CARE DECISIONS. AS A RESULT, THERE IS A $9 BILLION OVER-THE-COUNTER MARKET FOR DRUGS. THAT MAKES YOU IMPORTANT FROM A HEALTH AND ECONOMIC STAND POINT.

BUT DECISIONS ABOUT MEDICINES FOR SKIN RASHES OR STOMACH ACHES OR CHEST COLDS ARE NOT TRIVIAL. THEY REQUIRE A SUBSTANTIAL AMOUNT OF INFORMATION AND A SAFE AND EFFECTIVE DRUG PRODUCT.

THAT IS WHAT THE LAW REQUIRES, AND I KNOW THAT IS WHAT YOU ENDEAVOR TO PROVIDE TO CONSUMERS.

THE OVER-THE-COUNTER DRUG INDUSTRY GETS LITTLE ATTENTION FROM CONGRESS, ALTHOUGH I WOULD GUESS THAT MANY OF YOU THINK THAT IS JUST FINE. ON SOME MATTERS, YOU ALSO DO NOT GET AS MUCH OF FDA'S ATTENTION AS YOU NEED. THAT IS BAD.

OVER-THE-COUNTER REVIEW

THE OVER-THE-COUNTER DRUG REVIEW IS A PERFECT EXAMPLE OF FDA GIVING YOU TOO LITTLE TIME.

CONSUMERS GENERALLY ARE QUITE CONFIDENT IN OVER-THE-COUNTER MEDICINES. I ASSUME IT STEMS FROM THEIR EXPERIENCE, AND ALSO FROM THEIR BELIEF THAT GOVERNMENT WOULD NOT LET A DRUG BE SOLD IF THERE WERE ANY PROBLEMS. BUT AFTER 15 YEARS, FDA STILL HAS A LONG WAY TO GO IN COMPLETING ITS REVIEW, AND YOU HAVE MANY IMPORTANT PRODUCTS THAT LACK THE FDA STAMP OF APPROVAL AS EFFECTIVE.

YOU RISK THE LOSS OF CONSUMER CONFIDENCE AS THE REVIEW DRAGS ON. CONSUMERS RISK WASTING MILLIONS OF DOLLARS ON INEFFECTIVE PRODUCTS AND FOREGOING EFFECTIVE RELIEF THROUGH OTHER PROVEN MEDICINES.

I AM PAINFULLY AWARE OF THE LIMITED RESOURCES AT FDA. THE FDA'S OTC REVIEW STAFF NEEDS MORE PEOPLE; BUT, SO DO MANY OTHER IMPORTANT FUNCTIONS AT FDA. I SYMPATHIZE WITH COMMISSIONER YOUNG'S DILEMMA.

THE ADMINISTRATION AND THE CONGRESS HAVE NOT GIVEN FDA THE ADDITIONAL STAFF THAT ARE NEEDED. UNDER THESE ADVERSE CIRCUMSTANCES, I STRONGLY URGE YOU NOT TO BE PASSIVE. IT IS CONSUMER CONFIDENCE IN YOUR PRODUCTS THAT IS AT STAKE. IT IS IN YOUR INTEREST TO DO EVERYTHING YOU CAN TO ASSIST THE FDA, AND EVEN TO PUSH THE FDA TO COMPLETE THE OTC REVIEW PROMPTLY.

SWITCHING RX TO OTC

ANOTHER AREA WHERE I KNOW YOU WOULD LIKE TO SEE GREATER FDA ATTENTION IS IN SWITCHING PRESCRIPTION DRUGS TO OVER-THE-COUNTER STATUS. AS WITH SO MANY FDA DECISIONS, THIS ONE INVOLVES PROS AND CONS.

SWITCHING DRUGS FROM PRESCRIPTION CONTROLS RECOGNIZES THE PUBLIC'S DESIRE TO MAKE THEIR IMPORTANT HEALTH CARE DECISIONS. IT GIVES THEM MORE EFFECTIVE TOOLS TO TREAT THEMSELVES. AS MORE POWERFUL PRESCRIPTION DRUGS ARE SUGGESTED FOR OTC STATUS, THOUGH, WE MUST ALSO RECOGNIZE THAT MORE AND BETTER INFORMATION IS NECESSARY.

DOCTORS GO THROUGH YEARS OF DIAGNOSTIC AND TREATMENT TRAINING FOR A REASON. CONSUMERS MUST FULLY UNDERSTAND THE DRUGS THEY TAKE AND BE SUFFICIENTLY RESPECTFUL OF THEIR RISKS. CONSUMERS MUST NEVER BE ENTICED BY SUBTLE ADVERTISING TO TAKE DRUGS FOR UNTESTED OR UNPROVEN INDICATIONS.

SWITCHING PRESCRIPTION DRUGS TO OTC STATUS REQUIRES CONSIDERABLE

MEDICAL AND SCIENTIFIC JUDGEMENT. IT ALSO CAN PRODUCE ENORMOUS ECONOMIC GAINS FOR INDUSTRY. I EXPECT THAT FDA'S DECISIONS WILL BE THE RESULT OF SCIENTIFIC SCRUTINY ONLY. I TRUST FDA TO RESIST THE INEVITABLE POLITICAL PRESSURE FROM OTHERS WITH A VESTED INTEREST OR AN IDEOLOGICAL BENT TO MARKET POWERFUL DRUGS DIRECTLY TO THE CONSUMER.

ADVERTISING and NEW ERA

SELLING MEDICINES DIRECTLY TO THE PUBLIC CARRIES A HEAVY BURDEN. YOU ARE LEGALLY AND MORALLY OBLIGATED TO LABEL AND ADVERTISE TRUTHFULLY, COMPLETELY, AND ACCURATELY.

THE SIGNIFICANCE OF YOUR COMMUNICATIONS WITH CONSUMERS, AND THE SCRUTINY THEY CURRENTLY RECEIVE, WILL ONLY INCREASE AS YOUR INDUSTRY ENTERS A NEW ERA.

OUR BIOMEDICAL RESEARCH ESTABLISHMENT IS CONSTANTLY PRODUCING DAZZLING NEW INFORMATION. SOME OF THAT, LIKE THE RECENT STUDY OF ASPIRIN AND HEART ATTACKS, DIRECTLY AFFECTS THE OVER-THE-COUNTER INDUSTRY. IN ADDITION, YOU EXPECT NUMEROUS IMPORTANT PRESCRIPTION DRUGS TO BE SWITCHED TO OVER-THE-COUNTER STATUS.

WITH EACH OF THESE OTC "BREAKTHROUGHS", CONSUMERS WILL HAVE DIRECT ACCESS TO DRUGS WHICH HAVE FAR GREATER HEALTH CONSEQUENCES. FOR EXAMPLE, THE RECENT HEART STUDY IS NOT A RECOMMENDATION FOR ALL MEN AND WOMEN TO BEGIN A DAILY REGIMEN OF ASPIRIN. BUT YOU WOULD NOT KNOW THAT FROM THE RECENT SURGE IN ASPIRIN-HEART DISEASE RELATED ADVERTISING. NO

WHERE IS THE PUBLIC WARNED OF THE INCREASED RISK OF STROKE.

SUCH ADS FAIL TO FULLY AND FAIRLY INFORM THE PUBLIC WHO SHOULD NOT TAKE ASPIRIN. THEY ARE A DISSERVICE TO CONSUMERS AND A PUBLIC HEALTH HAZARD.

THESE RECENT ADS RAISE MANY OF THE SAME QUESTIONS AS DOES THE TELEVISION ADVERTISING OF PRESCRIPTION DRUGS. I STRONGLY OPPOSE CONSUMER DIRECTED PRESCRIPTION DRUG ADS BECAUSE THEIR SAFE AND EFFECTIVE USE REQUIRES PROFESSIONAL MEDICAL JUDGEMENT WHICH CONSUMERS DO NOT POSSESS.

CONSUMERS LACK THE NECESSARY EXPERTISE TO KNOW WHEN A PRESCRIPTION DRUG SHOULD BE USED. THE ADVERTISMENT, THEN, SERVES NO EDUCATIONAL PURPOSE. ITS SOLE FUNCTION IS TO INCREASE CONSUMER PRESSURE ON PHYSICIANS.

THE SAME RATIONALE IS APPLICABLE TO ANY OVER-THE-COUNTER MEDICINE THAT CAN CAUSE SIGNIFICANT HARM IF TAKEN BY THE WRONG PEOPLE OR FOR THE WRONG USE.

AS YOU DEVELOP NEW ADVERTISING STRATEGIES, AND AS YOU CONSIDER YOUR LABELING AND OTHER PROMOTIONAL MATERIAL, YOU HAVE THE OPPORTUNITY TO ADVANCE THE IMPORTANT SOCIETAL GOAL OF SELF CARE. WITH PROPER RESTRAINT, YOUR BUSINESS INTERESTS CAN COINCIDE WITH THE PUBLIC'S INTEREST.

THAT IS WHERE I HOPE THE OVER-THE-COUNTER DRUG INDUSTRY WILL ALWAYS BE.

PRODUCT LIABILITY

THERE IS ONE OTHER AREA THAT I THOUGHT WOULD BE OF INTEREST TO YOU - PRODUCT LIABILITY.

IN RECENT YEARS, THERE WERE A NUMBER OF BILLS THAT WERE INTRODUCED AND DEBATED, LARGELY IN THE SENATE. ALTHOUGH PORTRAYED AS ATTEMPTING TO INTRODUCE NATIONAL UNIFORMITY AND FAIRNESS INTO THE LAW OF PRODUCT LIABILITY, MOST OF THOSE BILLS WERE SIMPLY DESIGNED TO TAKE AWAY FROM INJURED CONSUMERS MANY OF THEIR RIGHTS TO RECOVERY. WE WATCHED THOSE BILLS CAREFULLY, BUT WERE NEVER FACED WITH SERIOUS ACTION IN THE HOUSE.

IN THIS CONGRESS, THINGS HAVE BEEN QUITE DIFFERENT. THE SUBCOMMITTEE WITH JURISDICTION OVER THIS ISSUE HAS NOW REPORTED OUT A BILL THAT SOON WILL COME BEFORE THE FULL COMMITTEE ON ENERGY AND COMMERCE.

I MUST STATE THAT I AM EXTREMELY DISAPPOINTED THAT THE COMMITTEE IS MOVING TO MARKUP THIS LEGISLATION SO QUICKLY.

THE VERSION OF THE LEGISLATION BEFORE THE COMMITTEE WAS DEVELOPED BEHIND CLOSED DOORS AND MOVED THROUGH THE SUBCOMMITTEE AS A PACKAGE

DEAL BETWEEN A HANDFUL OF MEMBERS ANU CERTAIN REPRESENTATIVES OF THE BUSINESS COMMUNITY.

IT WAS DEVELOPED WITHOUT SIGNIFICANT INPUT FROM CONSUMER GROUPS, LABOR, OR OTHER INTERESTED PARTIES.

AT THE MARKUP OF THIS BILL BEFORE THE SUBCOMMITTEE, I OFFERED A NUMBER OF AMENDMENTS. I BELIEVE THOSE AMENDMENTS ARE CRITICAL IF THIS DRAFT IS TO BE TRANSFORMED INTO A RESPONSIBLE BALANCE BETWEEN THE INTERESTS OF MANUFACTURERS AND THOSE OF CONSUMERS WHO ARE INJURED BY DEFECTIVE PRODUCTS.

THIS IS A COMPLICATED BILL, ON A COMPLEX SUBJECT. IT PROPOSES TO ASSERT FEDERAL JURISDICTION OVER THE LAW OF PRODUCT LIABILITY, AN AREA THAT TRADITIONALLY HAS BEEN UNDER STATE JURISDICTION. IT CONTAINS MANY LEGAL TERMS THAT WILL BE SUBJECT TO INTERPRETATION IN THOUSANDS OF LAWSUITS ALL OVER THE COUNTRY.

I HAVE BEEN SUPPORTIVE OF EFFORTS TO PROVIDE THIS COMPLEX AREA WITH THE CAREFUL SCRUTINY AND THOROUGH CONSIDERATION IT DESERVES. I AM WORKING CLOSELY WITH SEVERAL GROUPS, INCLUDING THE PROPRIETARY ASSOCIATION, AND WITH OTHER MEMBERS TO ATTEMPT TO IMPROVE THIS BILL AND OFFER CONSUMERS WHO ARE KILLED AND INJURED BY DEFECTIVE PRODUCTS A FAIR CHANCE TO BE COMPENSATED FOR THEIR INJURIES.

BEFORE I FINISH I WOULD LIKE TO TOUCH ON THE PART OF THE PROPOSED PRODUCT LIABILITY LEGISLATION THAT I KNOW IS OF MAJOR CONCERN TO YOU --

THE "GOVERNMENT STANDARDS" DEFENSE.

I UNDERSTAND FULLY THE ARGUMENT THAT A MANUFACTURER WHOSE PRODUCT HAS MET A STRICT GOVERNMENT STANDARD SHOULD NOT BE SUBJECT TO PUNITIVE DAMAGES FOR CONDUCT WITHIN THE SCOPE OF WHAT THE FOOD AND DRUG ADMINISTRATION LOOKED AT IN THE REVIEW PROCESS. THAT IS NOT NECESSARILY A POSITION THAT I WOULD PRESS FOR MYSELF, BUT I DO UNDERSTAND WHAT YOU ARE LOOKING FOR.

WHAT I THINK WE MUST KEEP IN MIND IS THAT ANY PROVISION THAT GIVES A GOVERNMENT STANDARD DEFENSE SHOULD NOT APPLY WHERE THE MANUFACTURER ENGAGED IN INTENTIONAL AND WRONGFUL CONDUCT THAT IS NOT ADDRESSED BY A GOVERNMENT STANDARD.

SUCH SITUATIONS INEVITABLY ARISE BECAUSE THE DRUG AND DEVICE APPROVAL PROCESS CANNOT POSSIBLY DISCOVER ALL THE PROBLEMS THAT MAY ARISE WITH A NEW DRUG OR NEW DEVICE. ONCE A COMPANY KNOWS THAT ITS DRUG OR DEVICE MAY HARM PEOPLE IN A WAY THAT IS UNEXPECTED, IT SHOULD NOT BE IMMUNE FROM PUNITIVE DAMAGES IF ITS CONDUCT IS WRONGFUL.

I AM CONCERNED THAT THE EFFECT OF THE PROVISION ADOPTED BY THE SUBCOMMITTEE WOULD BE TO CREATE AN INCENTIVE FOR MANUFACTURERS TO ADOPT A KNOW-NOTHING, DO-NOTHING POLICY ABOUT THE SIDE EFFECTS OF THEIR DRUGS AND DEVICES AFTER THEY ARE ON THE MARKET. THIS IS BECAUSE ALL THEY WOULD HAVE TO DO IS FOLLOW FDA REGULATIONS REGARDING REPORTING AND RELABELING AND NOTHING MORE. IN MANY CASES WHERE SERIOUS AND UNEXPECTED ADVERSE REACTIONS OCCUR, MUCH MORE MUST BE DONE TO PROTECT

THE PUBLIC.

THE IMPORTANT QUESTIONS IN DETERMINING WHETHER THERE SHOULD BE A BAR TO PUNITIVE DAMAGES ARE (1) WHETHER THE COMPANY ACTED WRONGFULLY ONCE IT KNEW THAT CONSUMERS WERE LIKELY TO BE HURT BY THE DRUG, AND (2) WHETHER THE COMPANY ACTED, OR DID NOT ACT, AT THE DIRECTION OR REQUEST OF THE FDA.

I INTEND TO OFFER AN AMENDMENT THAT WILL BE FAIR TO BOTH DRUG MANUFACTURERS AND INJURED CONSUMERS.

MY AMENDMENT WOULD PRECLUDE PUNITIVE DAMAGES FOR A DRUG, INCLUDING AN OVER-THE-COUNTER DRUG THAT HAS AN NDA OR A FINAL MONOGRAPH, OR DEVICE THAT WAS APPROVED FOR SAFETY AND EFFICACY BY THE FDA UNLESS THE MANUFACTURER:

-- INTENTIONALLY AND WRONGFULLY WITHHELD OR MISREPRESENTED INFORMATION REQUIRED FOR APPROVAL OR INFORMATION ON ADVERSE REACTIONS REQUIRED TO BE SUBMITTED AFTER APPROVAL;

-- ENGAGED IN OTHER INTENTIONAL AND WRONGFUL CONDUCT, TAKEN AFTER THE DRUG WAS APPROVED, THAT THE MANUFACTURER KNEW

WOULD BE LIKELY TO RESULT IN HARM TO AN INDIVIDUAL, UNLESS THE CONDUCT RESULTED FROM A DIRECTION OF THE FDA;

-- UNDERTOOK ILLEGAL CONDUCT RELATING TO THE SAFETY OR EFFICACY OF A DRUG UNDER ANY STATE LAW (SUCH AS A STATE LAW GOVERNING THE APPROVAL OR THE LABELING OF A DRUG).

-- THE IMMUNITY PROVIDED BY MY AMENDMENT WOULD EXTEND TO COMPLIANCE WITH TAMPER-RESISTANT PACKAGING REQUIREMENTS

PREDICTIONS ABOUT THE ULTIMATE FATE OF PRODUCT LIABILITY LEGISLATION REQUIRE A CRYSTAL BALL BETTER THAN MINE. ALL I CAN TELL YOU IS THAT IT WILL BE CONTROVERSIAL AND HARD-FOUGHT.

IN CLOSING, LET ME WISH YOU AND YOUR CONFERENCE EVERY SUCCESS.